IACUC POLICIES, PROCEDURES, and GUIDELINES

REVIEW OF JOINT VA-UK PROTOCOLS

Purpose:

This document establishes policies and procedures for the IACUC review of animal use activities that are primarily located at the Lexington Veterans Affairs Medical Center (Lexington VA) but involve activities requiring review and oversight by the University of Kentucky and the University of Kentucky IACUC (UK IACUC). This SOP does not apply to non-surgical procedures in research animals lasting less than 12 hours.

Background:

Investigators at the Lexington VA have established collaborative relationships with University of Kentucky investigators or share the use of equipment located at the University of Kentucky. These investigators house their animals at the Lexington VA Veterinary Medical Unit (VMU) under animal use protocols reviewed and approved by the Lexington VA Institutional Animal Care and Use Committee (VA IACUC). In pursuing the collaborative arrangements or use of shared equipment, they transport vertebrate animals to facilities under the jurisdiction and oversight of the University of Kentucky and the University of Kentucky IACUC. This requires that the investigator submit and receive approval from both the VA IACUC and the UK IACUC for the animal activities and places the respective IACUCs in the position of possibly reviewing animal activities approved at another Institution.

As stated in NOT-OD-01-017 (February 12, 2001),

“OLAW and APHIS agree that review of a research project or evaluation of a program or facility by more than one recognized IACUC is not a federal requirement……

If both institutions have full PHS Assurances, they may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be performed. It is recommended that if an IACUC defers protocol review to another IACUC, then documentation of the review should be maintained by both committees. Similarly, an IACUC would want to know about any significant questions or issues raised during a semiannual program inspection by another IACUC of a facility housing a research activity for which that IACUC bears some responsibility or exposure.”

The Lexington VA uses the standard paper-based VA Animal Component of Research Protocol (ACORP) form. The University of Kentucky uses an electronic protocol submission and approval system (e-Sirius®). This document establishes procedures designed to permit each Institution to fulfill their responsibilities and review the appropriate components of a specific vertebrate animal research proposal without posing a greater burden than is necessary upon the investigator or the respective IACUCs.

Administratively Revised September 17, 2014
Responsibilities:

The Memorandum of Understanding between the University of Kentucky and the Lexington Veterans Affairs Medical Center establishes the requirements for IACUC review, approval, and oversight for protocols involving the resources of both Institutions. The following two criteria require that a Lexington VA investigator obtain review, approval, and oversight by the UK IACUC for an animal activity primarily performed under a protocol approved by the VA IACUC:

1) The animal is housed at the University of Kentucky for greater than 12 hours.

2) Surgical manipulations are performed at the University of Kentucky.

In both of these situations, the investigator is subject to review, approval, and oversight by the UK IACUC and is subject to the rules and regulations of the University of Kentucky. As stated in the Memorandum of Understanding, “The VA IACUC may not grant permission for the use of University resources where approval by the University’s IACUC is required. Similarly, the University’s IACUC may not grant permission for the use of VA resources where approval by the VA IACUC is required.”

Due to ongoing construction at the VMU animal facility a new MOU between the UK and VAMC was established on June 1, 2014. This MOU allows for the transfer of animals to DLAR facilities during the construction period and describes each parties’ responsibilities during this period.

The construction period is expected to be two years at which time animals may be returned to the VMU animal facility and the applicable MOU may be terminated.

Procedures for Joint Protocol Processing

1. Investigators with approved VA ACORPs desiring to add components requiring UK IACUC approval must submit either an amendment/modification or new protocol (which ever the case may be) requests to both the UK IACUC and the VA IACUC. In the case of an amendment, these requests should be submitted simultaneously because approval from both IACUCs is required prior to the initiation of any activities requested in the amendment/protocol. In the case of a new protocol, the VA protocol will be approved first so that the ACORP may be attached to the UK protocol. Investigators planning to submit a joint protocol must first notify the VMU supervisor. The supervisor will initiate the UK IACUC e-Sirius® amendment/protocol. If the UK activity comes in the form of an amendment, then the amendment’s reason/purpose should state “UK/VA joint protocol” followed by the amendment’s identification number. Prior to submission of an amendment/protocol requesting UK IACUC approval of an activity listed in a VA-approved ACORP, an electronic copy of the complete approved VA ACORP (Adobe Acrobat PDF format) is attached by the VA Research Staff to the Title page of the “skeleton” e-Sirius® protocol. VA amendments and modifications are sequentially numbered and attached to the ACORP with the appropriate appendices and approvals associated with each modification. Unlike in the UK e-Sirius® system, the original VA ACORP is not automatically modified to reflect amendments approved after the initial protocol approval. Amendments to VA ACORPs and new VA protocols requiring UK IACUC approval must be submitted via the e-Sirius® protocol system. Investigators must access the system with their log-on and password and complete the unfinished amendment, created by the VMU supervisor in Item 1. This can be done by clicking on the protocol number, selecting and
completing the pages listed in Item 4, and submitting the amendment to the UK IACUC Office. The amendment/e-Sirius protocol should describe the animal-related activities proposed to be performed at the University of Kentucky. The investigator does not need to complete the entire e-Sirius® protocol form as the attached VA-approved protocol will provide adequate details regarding the other protocol activities at the VA to permit review by the UK IACUC. The following e-Sirius pages/fields must be included in the amendment/e-Sirius® protocol to permit UK IACUC review and approval:

a. **Experimental Design: Animal Methodology**: Description of the activities proposed to be performed at the University of Kentucky. This section should be limited to only those activities being performed at the University of Kentucky and for which UK IACUC approval is being sought. The activities should be identical to that requested under question #3 of the VA form “Modification of the Animal Component of Research Protocol (ACORP)” if submitted as an amendment.

b. **Species: Animal Usage Location** Where the animals will be held (>12 hours) or be surgically manipulated. This is required to ensure that the site(s) is (are) included in the UK IACUC semiannual facility and program review.

c. **Personnel**: Any personnel not listed on the VA ACORP and involved in the animal activities at the University of Kentucky must be listed.

2. The amendment/e-Sirius® protocol must be submitted by the principal investigator using their e-Sirius® logon and password. The submitted amendment/new protocol will be reviewed by the UK IACUC following standard policies and procedures for all amendments/new protocols using the designated review process. The UK IACUC Office will ensure that the appropriate VA documents have been attached to the e-Sirius® “skeleton” protocol prior to submitting the request for IACUC review and approval via Designated Review. The investigator will receive e-mail communications regarding the UK IACUC review through the e-Sirius® system.

3. The UK IACUC will be responsible for ensuring that the University of Kentucky animal housing and usage sites listed on the protocol are included in the UK semiannual facility and program review.

4. The annual review process for non-USDA covered species is deferred to the VA IACUC.

5. The VMU supervisor must be notified prior to animals being transported to and returned from UK facilities.

References:


2. UK/VA Memorandum of Understanding, 07/31/2009

3. UK/VA Memorandum of Understanding, 06/01/2014

Approved and Adopted by the Institutional Animal Care and Use Committee
September 16, 2009

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October 17, 2012

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